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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Masahide HOSHINO, et al.

GAU: 1614

SERIAL NO: New Divisional Application

EXAMINER: OSTRUP, Clinton T.

FILED: HEREWITH

FOR: DERMATOLOGIC PREPARATIONS

REQUEST FOR PRIORITY

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313

SIR:

☒ Full benefit of the filing date of U.S. Application Serial Number 09/926,270, filed October 04, 2001, and the International Stage of this application, PCT/JP00/01383, filed March 8, 2000, is claimed pursuant to the provisions of 35 U.S.C. §120.

☐ Full benefit of the filing date(s) of U.S. Provisional Application(s) is claimed pursuant to the provisions of 35 U.S.C. §119(e):

Application No.

Date Filed

☒ Applicants claim any right to priority from any earlier filed applications to which they may be entitled pursuant to the provisions of 35 U.S.C. §119, as noted below.

In the matter of the above-identified application for patent, notice is hereby given that the applicants claim as priority:

COUNTRY

Japan

APPLICATION NUMBER

11-101076

MONTH/DAY/YEAR

April 8, 1999

A Certified copy of the corresponding Convention Application

☐ are submitted herewith

☐ will be submitted prior to payment of the Final Fee

☐ were filed in prior application Serial No. filed

☒ was submitted to the International Bureau in PCT Application Number PCT/JP00/01383.

☐ (A) Application Serial No.(s) were filed in prior application Serial No. filed ; and

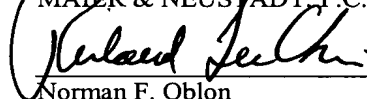
☐ (B) Application Serial No.(s)

☐ are submitted herewith

☐ will be submitted prior to payment of the Final Fee

Respectfully Submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.



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## PATENT COOPERATION TREATY

PCT

NOTICE INFORMING THE APPLICANT OF THE  
COMMUNICATION OF THE INTERNATIONAL  
APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

From the INTERNATIONAL BUREAU

To:

ARUGA, Mitsuyuki  
Kyodo Building  
3-6, Nihonbashiningyocho 1-chome  
Chuo-ku  
Tokyo 103-0013  
JAPON



Date of mailing (day/month/year) 19 October 2000 (19.10.00)		IMPORTANT NOTICE	
Applicant's or agent's file reference FP-KS-0548			
International application No. PCT/JP00/01383	International filing date (day/month/year) 08 March 2000 (08.03.00)	Priority date (day/month/year) 08 April 1999 (08.04.99)	
Applicant KAO CORPORATION et al			

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:  
US

In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:  
CN,EP,JP

The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on 19 October 2000 (19.10.00) under No. WO 00/61097

**REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)**

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

**REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))**

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No. (41-22) 740.14.35	Authorized officer  J. Zahra  Telephone No. (41-22) 338.83.38
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COPY

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP00/01383

## I. Basis of the report

## 1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed
- ☐ the description:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the claims:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, as amended (together with any statement under Article 19  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the drawings:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the sequence listing part of the description:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/fig \_\_\_\_\_

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference FP-KS-0548	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP00/01383	International filing date (day/month/year) 08 March 2000 (08.03.00)	Priority date (day/month/year) 08 April 1999 (08.04.99)
International Patent Classification (IPC) or national classification and IPC A61K 7/48, 7/00, 7/06, C07C 233/18		
Applicant KAO CORPORATION		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of \_\_\_\_\_ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 23 August 2000 (23.08.00)	Date of completion of this report 31 January 2001 (31.01.2001)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

COPY

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP00/01383

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims	1-7	YES
	Claims		NO
Inventive step (IS)	Claims	1-7	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-7	YES
	Claims		NO

**2. Citations and explanations****List of Documents Cited**

Document 1: US, 3773056, A (Kalopissis et al.), 20 November, 1973 (20.11.73)

Document 2: JP, 10-218849, A (Kao Corporation), 18 August, 1998 (18.08.98)

**Explanation****1. Novelty**

The subject matters of claims 1-7 appear to be novel.

The technical features of the inventions of claim 1-5 are considered to be external application compositions blended with diamide derivatives expressed by the general formula (1) of claim 1, having the effects of holding humidity and strengthening the skin barrier function. The technical feature of the subject matters of claims 6 and 7 is that in the diamide derivatives expressed by the general formula (1), hydrocarbyl groups with a specific number of carbon atoms are selected as the radical  $R^3$  in the formula. Nonetheless, none of the cited documents show diamide derivatives in which specific hydrocarbyl groups are selected as the radical  $R^3$  or the radical  $R^1$  in the formula, nor the external application compositions containing these diamide derivatives.

**2. Inventive step**

The subject matters of claims 1-7 are considered to involve inventive steps in view of documents 1 and 2 cited in the ISR.

As stated in 1. Novelty, the external application compositions for skin or the diamide derivatives of claims 1-7 are not described in either document 1 or 2, and it is considered that a person skilled in the art could not have easily conceived of selecting the compositions in which hydrogen atoms are bonded to both of the nitrogen atoms in the general formula (1) and which have hydrocarbyl groups with specific numbers of carbons as the radicals  $R^3$  and  $R^1$  of the formula in order to obtain diamide derivatives having the effects of holding humidity, reinforcing the skin barrier function and the like. Further, the subject matters of claims 1-7 are not only effective in holding humidity and improving chapped skin as confirmed by the test results shown in Tables 3 and 4 of the specification, but also are excellent in blending properties and blending stability.

**3. Industrial applicability**

Industrial applicability of the subject matters of claims 1-7 is as indicated in documents 1 and 2 which disclose the same and/or similar arts.

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/JP00/01383

## A. CLASSIFICATION OF SUBJECT MATTER

Int.Cl<sup>7</sup> A61K 7/48, 7/00, 7/06, C07C 233/18

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Int.Cl<sup>7</sup> A61K 7/00-7/50, C07C 233/18

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
CA (STN), REGISTRY (STN), WPIDS (STN)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, 3773056, A (Kalopissis et al.),	1-3
A	20 November, 1973 (20.11.73), Columns 3, 9, 11, lines 15 to 26 (Family: none)	4-7
A	JP, 10-218849, A (Kao Corporation), 18 August, 1998 (18.08.98), Claims (Family: none)	1-7

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

\* Special categories of cited documents:  
 "A" document defining the general state of the art which is not considered to be of particular relevance  
 "E" earlier document but published on or after the international filing date  
 "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)  
 "O" document referring to an oral disclosure, use, exhibition or other means  
 "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention  
 "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone  
 "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art  
 "&" document member of the same patent family

Date of the actual completion of the international search  
10 May, 2000 (10.05.00)

Date of mailing of the international search report  
23 May, 2000 (23.05.00)

Name and mailing address of the ISA/  
Japanese Patent Office

Authorized officer

Facsimile No.

Telephone No.

## PATENT COOPERATION TREATY



## PCT

**NOTIFICATION OF TRANSMITTAL  
OF COPIES OF TRANSLATION  
OF THE INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

(PCT Rule 72.2)

From the INTERNATIONAL BUREAU

To:

ARUGA, Mitsuyuki  
Kyodo Building  
3-6, Nihonbashiningyocho 1-chome  
Chuo-ku  
Tokyo 103-0013  
JAPON

Date of mailing (day/month/year) 30 August 2001 (30.08.01)	<b>IMPORTANT NOTIFICATION</b>
Applicant's or agent's file reference FP-KS-0548	
International application No. PCT/JP00/01383	International filing date (day/month/year) 08 March 2000 (08.03.00)
Applicant KAO CORPORATION et al	

**1. Transmittal of the translation to the applicant.**

The International Bureau transmits herewith a copy of the English translation made by the International Bureau of the international preliminary examination report established by the International Preliminary Examining Authority.

**2. Transmittal of the copy of the translation to the elected Offices.**

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following elected Offices requiring such translation:

EP,CN,US

The following elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

JP

**3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).**

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report.

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No. (41-22) 740.14.35	Authorized officer  Eliott PERETTI  Telephone No. (41-22) 338.83.38
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